Kala Pharmaceuticals Reports Fourth Quarter and Full Year 2017 Financial Results

March 26, 2018

-- Update on dry eye clinical data --

-- PDUFA target action date for INVELTYS ™is August 24, 2018 –

-- Business update call at 8:00 AM ET today --

WALTHAM, Mass.--(BUSINESS WIRE)--Mar. 26, 2018-- Kala Pharmaceuticals, Inc. (NASDAQ:KALA), a biopharmaceutical company focused on the development and commercialization of product candidates using its proprietary mucus-penetrating particle (MPP) technology, today reported financial results for the fourth quarter and full year 2017.

"This last year included significant accomplishments for Kala, marked by a successful initial public offering, and the acceptance of a New Drug Application for INVELTYS™ (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery with a PDUFA target action date of August 24, 2018," said Mark Iwicki, Chairman and Chief Executive Officer of Kala Pharmaceuticals. "Additionally, in January 2018, we reported topline results from two Phase 3 clinical trials of KPI-121 0.25%, STRIDE 1 and STRIDE 2, in patients with dry eye disease. Since January, we have been conducting additional analyses of the data from these two Phase 3 trials and the Phase 2 study. These analyses are being done to better understand the results and to prepare for discussions with the Food and Drug Administration. We expect to meet with the FDA to develop our path forward and will provide further updates following that meeting."

Recent Corporate Highlights

- **Completed initial public offering** in July of 6,900,000 shares of common stock, including the underwriters' exercise in full of their option to purchase additional shares, at the public offering price of $15.00 per share. The exercise of the underwriters' option brought the amount of gross proceeds raised in the offering to approximately $103.5 million, or $94.0 million in net proceeds after underwriting discounts and expenses.
- **Ended 2017 with $114.6 million** in cash.
- **Submitted and announced acceptance for review of a New Drug Application (NDA) for INVELTYS** for the treatment of inflammation and pain following ocular surgery. The NDA submission is supported by positive data from two Phase 3 trials. If approved, Kala expects that INVELTYS would be the first twice-daily ocular corticosteroid indicated for the treatment of post-operative ocular inflammation and pain.
- **Reported topline results** from two Phase 3 clinical trials of KPI-121 0.25% - STRIDE 1 and STRIDE 2 – in patients with dry eye disease.
    - Achieved statistical significance for the primary sign endpoint of conjunctival hyperemia at Day 15 in the ITT population in both trials.
    - Achieved statistical significance for the primary symptom endpoint of ocular discomfort severity at Day 15 in the ITT population in STRIDE 1 with a trend towards a treatment effect in STRIDE 2.
    - Achieved statistical significance for the second primary symptom endpoint of ocular discomfort severity at Day 15 in patients with a more severe baseline discomfort in STRIDE 1 with a strong trend towards a treatment effect observed for the same endpoint in STRIDE 2.
    - Positive treatment effects were also observed for symptom endpoint of ocular discomfort severity in the ITT population at Day 8 in both trials, which was a key pre-specified secondary endpoint.
    - KPI-121 0.25% was well-tolerated in both trials with elevation in intra-ocular pressure, a known side effect with topical corticosteroids, similar to placebo.
- **Additional analyses of STRIDE 1, STRIDE 2 and Phase 2 data**
    - Kala conducted additional analyses on a post-hoc basis to better understand the data on KP1-121 0.25% for patients with dry eye disease.
        - **Phase 2 ocular discomfort data using the analysis method defined in the Phase 3 statistical analysis plan:** Kala observed a positive treatment effect for ocular discomfort at day 15 ($p=0.0489$) using this analysis method. Additionally, a similar magnitude of effect was observed in the Phase 2 trial as observed in STRIDE 1 (5.27 mm and 5.44 mm differences vs. vehicle, respectively).
        - **Pooled ITT populations from STRIDE 1 and STRIDE 2:** A positive treatment effect was observed for the primary symptom endpoint of ocular discomfort at day 15 ($p<0.0001$) in this pooled population. The pooled results in 2 exploratory analyses in subgroups defined by geographical regions of east and west achieved p-values of 0.0071 and 0.0021 respectively and north and south achieved p-values of 0.0002 and 0.0176, respectively.
        - **Effect on ocular discomfort on each of the days between days 8 and 14 in STRIDE 1 and STRIDE 2**

using the analysis that was pre-specified for day 15: P-values of less than 0.002 were observed for all days during that time period in STRIDE 1, and p-values less than 0.05 were observed on 6 of the 7 days during that time period in STRIDE 2.

- **Expanded expert leadership on the Board of Directors and management team and grew operations in preparation for commercialization**
  - Andrew Koven, President and Chief Business Officer at Aralez Pharmaceuticals, Inc., was appointed to the Board of Directors, bringing a diverse business development and legal expertise in the biotech and pharmaceuticals industry.
  - Gregory Perry, formerly Chief Financial Officer at Novelion Therapeutics, Inc., was appointed to the Board of Directors and as audit committee chair, bringing deep expertise in business, finance and strategy in the biotech industry.
  - Todd Bazemore, formerly Executive Vice President and Chief Operating Officer of Santhera Pharmaceuticals (USA), Inc., was appointed as Chief Operating Officer, bringing a proven track record and extensive experience in sales, marketing, market access, new product planning and business development strategy.

Fourth Quarter and Full Year 2017 Financial Results

- **Cash Position:** As of December 31, 2017, Kala had cash of $114.6 million compared to $45.5 million as of December 31, 2016. Kala anticipates that its existing cash on hand will enable it to fund operations for at least the next 12 months.
- **R&D Expenses:** For the quarter ended December 31, 2017, research and development expenses were $5.9 million compared to $6.9 million for the same period in 2016. The decrease in research and development expenses is primarily due to a decrease in costs associated with our Phase 3 clinical trial of INVELTYS which completed in the first half of 2017, and STRIDE 1 and 2 which completed during the fourth quarter of 2017. R&D expenses for the full year ended December 31, 2017 were $29 million compared to $25 million for the 12 months ended December 31, 2016. The increase in R&D expenses was primarily due to an increase in personnel costs as well as regulatory costs associated with our NDA filing for INVELTYS.
- **G&A Expenses:** General and administrative expenses for the quarter ended December 31, 2017 were $5.3 million compared to $1.3 million for the same period in 2016. G&A expenses for the full year ended December 31, 2017 were $10.9 million compared to $7.6 million for the same period in 2016. The increase in G&A expenses is primarily attributable to an increase in personnel costs and professional fees associated with operating as a public company, and costs incurred in preparation for becoming a commercial organization.
- **Operating Loss:** Loss from operations for the quarter ended December 31, 2017 was $11.1 million compared to $8.2 million for the same period in 2016. Loss from operations for the full year ended December 31, 2017 was $39.9 million compared to $32.7 million for the same period in 2016.
- **Net Loss:** Net loss was $11.3 million, or $0.46 per share, for the quarter ended December 31, 2017 compared to a net loss of $8.4 million, or $7.11 per share, for the same period in 2016. Net loss for the full year ended December 31, 2017 was $42.2 million, or $6.11 per share, compared to $33.2 million, or $28.07 net loss per share, for the same period in 2016. The decrease in net loss per share during the fourth quarter and full year 2017 compared to the same periods in 2016 is the result of the increase in the weighted average shares outstanding resulting from the conversion of our preferred stock into shares of common stock and from shares of common stock issued in connection with the initial public offering completed in July.

Conference Call Information

Kala will host a live conference call and webcast at 8:00 AM ET to discuss the Company's 2017 financial results and provide a business update. To access the conference call, please dial 866-300-4091 (domestic callers) and 703-736-7433 (international callers) five minutes prior to the start of the call and provide the conference ID: 7082747.

To access a live webcast and subsequent archived recording of the presentation, please visit "Events" in the "Investors" section of the Kala website at http://kalarx.com/.

About INVELTYS™ (KPI-121 1%)

INVELTYS™ (KPI-121 1%) is a twice-a-day corticosteroid for the treatment of inflammation and pain following ocular surgery. INVELTYS utilizes Kala's proprietary Mucus-Penetrating Particle (MPP) technology to enhance penetration into target tissues of the eye. In pre-clinical studies, MPP increased delivery of a corticosteroid into ocular tissues more than three-fold by facilitating penetration through the tear film mucus. Two Phase 3 clinical trials have been successfully completed for INVELTYS and statistical significance was achieved for both primary efficacy endpoints in both trials. In each of these trials, INVELTYS was well tolerated with no treatment-related serious adverse events observed. Kala believes INVELTYS has a favorable treatment profile compared to the standard of care for the treatment of inflammation and pain following ocular surgery, due to its twice-a-day dosing regimen and rapid onset of relief.

About KPI-121 0.25%

Kala is developing KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease utilizing a two-week course of therapy administered four times a day. Dry eye disease is a chronic, episodic, multifactorial disease affecting the tears and ocular surface and can involve tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. KPI-121 0.25% utilizes Kala's Mucus-Penetrating Particle

(MPP) technology to enhance penetration of loteprednol etabonate (LE) into target tissue of the eye. In preclinical studies, MPP technology increased delivery of LE into ocular tissues more than three-fold compared to current LE products by facilitating penetration through the tear film mucus. Kala has completed one Phase 2 and two Phase 3 clinical trials of KPI-121 0.25%. Kala believes that KPI-121 0.25%'s broad mechanism of action, rapid onset of relief of both signs and symptoms, favorable tolerability and safety profile and the potential to be complementary to existing therapies, could result in a favorable profile for the management of dry eye flares and other dry eye associated conditions which could benefit from temporary relief of dry eye signs and symptoms.

About Kala Pharmaceuticals, Inc.

Kala is a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary mucus-penetrating particle (MPP) technology, with an initial focus on the treatment of eye diseases. Kala has applied the MPP technology to a corticosteroid designed for ocular applications, resulting in two lead product candidates. The product candidates are INVELTYS™ (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery, for which an NDA has been accepted for review by the FDA, and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, that involve substantial risks and uncertainties, including statements regarding the development and regulatory status of the company's product candidates, including INVELTYS™ (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, and our expectations regarding our ability to fund our operating expenses with our cash on hand. All statements, other than statements of historical facts, contained in this press release, including statements regarding the Company's strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on such forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements as a result of various risks and uncertainties including, but not limited to: whether the data from our Phase 3 clinical trials of KPI-121 0.25% will warrant submission of an NDA on the timeline expected, or at all, whether any additional clinical trials will be required prior to submission of an NDA and whether any such NDA will be approved; that topline data is based on preliminary analysis of key efficacy and safety data, and such data could change following a more comprehensive review and may not accurately reflect the complete results of our clinical trials; that post-hoc analyses are normally given less weight by regulatory authorities than pre-specified analyses; whether our NDA for INVELTYS will be approved by its PDUFA date or at all; uncertainties inherent in the availability and timing of data from ongoing clinical trials; expectations for regulatory approvals to conduct trials or to market products; whether the Company's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements for the Company's expected timeline; other matters that could affect the availability or commercial potential of the Company's product candidates; and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, discussed in the "Risk Factors" section of the Company's most recently filed Quarterly Report on Form 10-Q and other filings the Company makes with the Securities and Exchange Commission. These forward-looking statements represent the Company's views as of the date of this release and should not be relied upon as representing the Company's views as of any date subsequent to the date hereof. The Company does not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Kala Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	December 31, 2017	December 31, 2016
Cash	$ 114,565	$ 45,472
Working Capital (1)	100,755	40,080
Total Assets	116,133	46,329
Convertible Preferred Stock	-	118,391
Total Stockholders' Equity/(Deficit)	89,679	(87,762)

(1) The Company defines working capital as current assets less current liabilities.

Kala Pharmaceuticals, Inc.
Consolidated Statement of Operations
(In thousands, except share and per share data)
(Unaudited)

	Quarter Ended December 31,	Year Ended December 31,

	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 5,880	$ 6,912	$ 29,008	$ 25,029
General and administrative	5,260	1,284	10,867	7,640
Total operating expenses	11,140	8,196	39,875	32,669
Loss from operations	(11,140)	(8,196)	(39,875)	(32,669)
Other income (expense):				
Interest income	251	57	527	147
Interest expense	(401)	(201)	(1,019)	(767)
Change in fair value of warrant liability	-	(55)	(1,844)	122
Total other income (expense)	(150)	(199)	(2,336)	(498)
Net loss attributable to common stockholders—basic and diluted	$ (11,290)	$ (8,395)	$ (42,211)	$ (33,167)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.46)	$ (7.11)	$ (6.11)	$ (28.07)
Weighted average shares outstanding—basic and diluted	24,515,612	1,181,429	6,903,239	1,181,429

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Investors and Media:
MacDougall Biomedical Communications
Cammy Duong, 781-591-3443
cduong@macbiocom.com